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Filed : October 25, 2001

REMARKS

Applicant acknowledges receipt of the Office Action mailed January 23, 2003 (Paper No. 8). In this Office Action, the Examiner has stated that the amendment to Claim 1 contained in the response to the previous Office Action overcame the rejection of the claims under 35 U.S.C. §112 and that the arguments put forth in the response were convincing, leading to a withdrawal of the rejection of the Claims 1 to 8 and 10 to 15 under U.S.C. §102(b). The latest Office Action contains new rejections, covering all 15 claims. To summarize, the PTO rejected Claim 1 under 35 U.S.C. §103(a) as being unpatentable over Ostlund et al. (U.S. Patent No. 5,550,166). In addition to this rejection, Claims 1 to 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over de la Harpe et al. (U.S. Patent No. 5,980,905) in view of the aforementioned Ostlund reference.

Claims 1-15 are pending in the application; Claim 1 has been amended to recite a method of reducing symptoms associated with Polycystic Ovary Syndrome (PCOS) comprising administering ... a composition comprising at least one purified chromium-containing compound. Claims 2, 5, and 15 have been amended to reflect the new definition of the chromic component of the composition of Claim 1 and to remove the term “chromium yeasts” from the list of forms of chromium that can be selected for use in Claim 1. New Claims 16-25 have been added; Claims 16 and 21 are independent claims similar to Claim 1, but with variations in the definitions of the chromic component of the composition. Support for the amendments and the new claims is provided in the original claims as filed and throughout the specification. Reconsideration and withdrawal of the present rejections in view of the amendments and comments presented herein are respectfully requested.

Claim 1 is not obvious

The PTO rejected Claim 1 under 35 U.S.C. §103(a) as being obvious in light of U.S. Patent No. 5,550,166, to Ostlund et al.. Under 35 U.S.C. §103(a), when considering obviousness rejections, a prior art reference must be considered in its entirety, i.e., as a whole, including portions that would teach away from the claimed invention. See W.L. Gore & Associates, Inc. v. Garlock Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983); M.P.E.P. §2141.02. Additionally,

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all the claim limitations must be taught or suggested by the prior art. See Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); M.P.E.P. §2143.03.

Ostlund et al. teach a composition and a method for the treatment of insulin resistance and related complications that contains or utilizes an effective amount of pinitol, a derivative of pinitol or a metabolite of pinitol. The specification of this patent suggests numerous optional ingredients that may be incorporated into the composition or used in the treatment method in addition to pinitol, including chromium yeast. While chromium is not an element of any claim in the Ostlund patent, each and every embodiment of the invention contains pinitol or a derivative or metabolite of pinitol. Pinitol and its derivatives and metabolites are the only chemical elements in the claims. Thus it is implied that pinitol, one of its derivatives or one of its metabolites is both necessary and sufficient for the treatment of insulin resistance and related complications with the compositions and methods taught by Ostlund. In contrast, our claims recite methods of treating PCOS by administering a composition comprising at least one chromium complex and our application is centered on the administration of chromium complexes for the treatment of PCOS. It contains no reference to pinitol or any other organic compound with a similar structure or function. The Ostlund reference serves to teach away from our invention, by teaching that the treatment of PCOS can be performed successfully using an organic compound with no mineral component whatsoever; no claim to any mineral component of any kind is made in the patent. Without the use of pinitol, a derivative of pinitol or a metabolite of pinitol, there is no reason to expect success in the treatment of PCOS, according to the information disclosed in Ostlund et al.. Thus the Ostlund reference cannot support an obviousness rejection of our claims.

Nevertheless, to emphasize the distinction between our invention and that of Ostlund, we have amended Claims 1, 2, 5, and 15 and added new claims 16-25 to exclude chromium yeasts as a possible form of chromium to be used in the invention. None of the remaining chromium forms are disclosed in the Ostlund patent. We therefore respectfully request the withdrawal of the objection to Claim 1 under 35 U.S.C. §103(a) in view of Ostlund et al..

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Claims 1-15 are not obvious

The PTO has also rejected all of the claims pending in the present application as being obvious in view of Ostlund et al. in combination with de la Harpe et al. (U.S. Patent No. 5,980,905). De la Harpe et al. teaches a composition comprising chromium polynicotinate, a cyclooxygenase inhibitor, an acid, a mucolytic, and a salicin-containing herb, as well as methods for using the composition to supplement dietary chromium, treat hyperglycemia, stabilize blood glucose, increase lean body mass, reduce body fat, and reduce high levels of blood serum lipids. The PTO has argued that one with skill in the art would have been motivated to use the composition of de la Harpe in light of the disclosures of Ostlund regarding the treatment of PCOS. In Ostlund et al., a method for treating PCOS is taught which uses pinitol to treat insulin resistance (IR), PCOS being one of the syndromes associated with IR. The patent also claims a composition containing pinitol for treating the conditions of IR, hyperlipidemia and dyslipidemia. The PTO asserts that since de la Harpe also provides a composition for the treatment of, and a method for, treating hyperlipidemia, that the composition of de la Harpe could be used for treating the conditions of IR as well. Applicant respectfully disagrees.

As discussed under M.P.E.P. §2143 and 2143.03, in order to establish a *prima facie* case for obviousness, certain basic criteria must be met. One of these criteria is that there must be some suggestion or motivation to combine reference teachings. Another is that there must be a reasonable expectation of success.

As previously discussed, the Ostlund patent teaches the use of a carbohydrate, pinitol, for the treatment of insulin resistance (IR) and disorders that are associated with IR. One of the harmful effects of IR, as described in Ostlund, is abnormal lipid profiles, including reduced high-density lipoprotein cholesterol, elevated low-density lipoprotein cholesterol and elevated triglycerides. De la Harpe teaches a composition comprising five elements and methods for using the composition for six purposes, which can be grouped into three categories: treating hyperglycemia/reducing serum glucose; increasing lean body mass/reducing body fat; and reducing high serum blood lipids. Hence the de la Harpe patent also contains a method for treating hyperlipidemia.

The PTO asserts that it would have been obvious to an individual with skill in the art to use the composition of de la Harpe to treat PCOS in light of the information disclosed in

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Ostlund, as Ostlund provides a link between PCOS and insulin resistance, and de la Harpe provides a method for the treatment of hyperlipidemia, which can be symptomatic of insulin resistance in a patient. However, the Ostlund reference claims a pinitol composition for treating conditions of IR, hyperlipidemia and dyslipidemia, as well as a method of specifically treating conditions of insulin resistance with pinitol, in order to treat disorders related to IR, such as PCOS. While the invention of de la Harpe teaches methods of treating conditions which can be hallmarks of insulin resistance, e.g. hyperlipidemia, dyslipidemia and abnormal glucose tolerance, there is no indication in the de la Harpe reference that the compositions and methods taught therein would be effective in the treatment of IR itself. Hyperlipidemia, dyslipidemia and abnormal glucose tolerance are not definitive signs of insulin resistance and can manifest in patients who are not afflicted with IR. For example, type 1 diabetes is the result of the destruction of the insulin-producing cells within the pancreas. Children with type 1 diabetes often manifest multiple symptoms of the disease, including elevated serum glucose levels and cardiovascular risk factors such as hyperlipidemia and hypercholesterolemia (Lipman TH et al. (2000) *Nursing Res.* **49**:160). However, these individuals are not displaying the symptoms of IR, but instead of an insufficient production of insulin by the pancreas. These patients have a normal response to the reduced amounts of insulin produced by their bodies and do not suffer from IR. Although the compositions and methods of de la Harpe could possibly be useful for treating hyperlipidemia and dyslipidemia that arises due to IR, there is no suggestion in de la Harpe that the compositions or methods disclosed therein would be effective at reducing IR itself, the underlying causes of IR or in treating other conditions which are closely associated with IR, and may indeed be caused by IR, such as PCOS. Given the lack of a definitive connection between the methods and compositions of de la Harpe and the purposes for the invention of Ostlund, there is no motivation to combine the teachings of the two references.

The Ostlund patent emphasizes the requirement for pinitol, a derivative of pinitol or a metabolite of pinitol in the treatment of IR. The de la Harpe patent does not mention IR and only discusses the treatment of conditions which may or may not be due to a patient having IR, as all of the conditions disclosed in the reference have multiple causes. As the composition and methods of De La Harpe lack pinitol, any derivative of pinitol, any metabolite of pinitol and any

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organic compound with a similar structure or function, there is no reason to believe that the composition of De La Harpe could be used successfully in the method claimed by Ostlund.

Since the two references in combination fail to meet the criteria for a *prima facie* case of obviousness, Applicant respectfully submits that Claims 1-15 are not obvious in light of the two patents and requests withdrawal of the PTO's rejection to the claims under 35 U.S.C. §103(a).

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CONCLUSION

In view of the foregoing remarks, Applicant respectfully submits that the present application is in condition for allowance. Nevertheless, the PTO is invited to contact the undersigned at the telephone number appearing below to discuss any remaining issues. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 4-21-03

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